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<b>(51) International Patent Classification <sup>5</sup>:</b> <b>A61M 15/08, B65D 75/38, 75/30, 75/56</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 94/19043</b> <b>(43) International Publication Date:</b> 1 September 1994 (01.09.94)
<b>(21) International Application Number:</b> PCT/EP94/00513 <b>(22) International Filing Date:</b> 18 February 1994 (18.02.94)  <b>(30) Priority Data:</b> 9303538.4      22 February 1993 (22.02.93)      GB  <b>(71) Applicant (for all designated States except US):</b> THE BOOTS COMPANY PLC [GB/GB]; 1 Thane Road West, Nottingham NG2 3AA (GB).  <b>(72) Inventor; and</b> <b>(75) Inventor/Applicant (for US only):</b> THEOBALD, Nigel, Colin [GB/GB]; The Boots Company plc, 1 Thane Road West, Nottingham NG2 3AA (GB).  <b>(74) Agent:</b> SMITH, Elizabeth, Jane; The Boots Company plc, Patents Dept., R4 Pennyfoot Street, Nottingham NG2 3AA (GB).		<b>(81) Designated States:</b> AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, ES, FI, GB, HU, JP, KP, KR, KZ, LK, LU, LV, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i>
<b>(54) Title:</b> MEDICAMENT PRESENTATION  <div data-bbox="292 1134 1331 1365"></div> <b>(57) Abstract</b> <p>A dispenser for administering a volatile liquid medicament comprises an inner container (2, 3) adapted to hold the liquid medicament (1), said inner container (2, 3) being permeable to vapour from the medicament (1), but substantially impermeable to the liquid medicament (1), and an outer container (4, 5) within which the first retaining means (2, 3), has been sealed, the outer container (4, 5) being impermeable to the medicament (1) as liquid or vapour.</p>		

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MEDICAMENT PRESENTATION

The present invention relates to means for presentation of medicaments, in particular to a form of packaging and dispensing volatile liquid medicaments  
5 such as decongestant inhalation products.

Decongestant inhalation products (for example those available commercially under the registered trademark Karvol) are highly volatile at room temperature. They are designed to be applied to a fabric substrate such as  
10 bed clothes or the clothing of the wearer prior to use so the volatile aromatic vapour produced can be inhaled by the user over a length of time. However, such medicaments are often sticky, and messy to apply to a fabric substrate. It would be advantageous to present  
15 the medicament in a form which allows slow release of vapour without the need to soil bed clothes or the like with the medicament.

The present invention provides a dispenser for administering a volatile liquid medicament comprising an  
20 inner container adapted to hold the liquid medicament, said inner container being permeable to vapour from the medicament, but substantially impermeable to the liquid medicament, and an outer container within which the first retaining means has been sealed, the outer  
25 container being impermeable to the medicament as liquid or vapour.

Preferably the dispenser comprises an absorbent solid substrate within the inner container onto which the liquid medicament is absorbed. The absorbent solid  
30 may be a woven or non-woven fabric, a synthetic or

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natural sponge, a foamed plastics material or paper, preferably tissue paper.

Preferably the inner container comprises a semi-permeable membrane over all or a portion of its surface.

- 5 The inner container may comprise a plastics material impermeable to aromatic liquids [e.g. polyvinylchloride (PVC) or a polyolefin] which is microperforated to allow passage of the vapour.

- The outer container preferably comprises a plastics material which may be a single material which is impermeable to the vapour of the volatile medicament, or it may comprise a composite of (a) a supporting layer of a plastics material which may on its own be permeable to the vapour but which has sufficient strength to protect the dispenser during manufacture, transport and display and (b) a layer or coating of a material which is impermeable to the vapour of the volatile medicament on the surface of the supporting layer which forms the inner surface of the outer container. The supporting layer may be a polyolefin homopolymer or copolymer or a polyvinylchloride homopolymer or copolymer. The impermeable layer may be formed by laminating a separate layer of impermeable material such as a plastics material (e.g. polyvinylidenechloride polymer) or metal (e.g. an aluminium) film to the supporting layer or by coating the supporting layer with an impermeable coating e.g. of polyvinylidenechloride polymer, aluminium, aluminium oxide or silicon oxide. Preferably the material from which the outer container is made is one which can be sealed to itself by the application of heat or high frequency welding. In one preferred embodiment the outer container is manufactured from two sheets which are sealed together around their periphery either by heat sealing or by the use of adhesive to enclose the
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- 3 -

inner container. In another embodiment, the outer container is formed by a backing member of a rigid plastics material which is impermeable to the liquid medicament and to the vapour thereof and a vapour-impermeable film sealed to the backing member enclosing the inner container. The inner container may also be formed by the backing member and a liquid-medicament-impermeable film sealed to the backing member to enclose either the liquid medicament or a substrate impregnated with the liquid medicament.

The medicament may comprise any liquid medicament which is volatile at room temperature, more preferably a decongestant inhalation product used for treating the symptoms of cold or flu, most preferably the medicament is an aromatic mixture of essential oils and spices such as pine oil, cinnamon oil and menthol for example that available from the applicant under the trade mark Karvol.

Preferably the single dose of liquid medicament is from about 0.1 ml to about 5 ml, more preferably from about 0.5 ml to about 2 ml, most preferably about 1 ml.

As well as being useful for decongestant inhalation products the medicament presentation of the present invention may be useful for other volatile liquid medicaments that are staining, are irritating to the skin, or noxious in some other way, the vapour of which is nevertheless therapeutic.

Where the inner container of the dispenser of the invention is removed from the outer container before use, the inner container may further comprise a means for attaching the inner container to an object. The attaching means may be an adhesive means such as an

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adhesive patch located on the outer surface of the inner container for attachment of the pack to a surface. The attaching means may be an engagement means mounted on or integral to the inner container such as a hook shaped  
5 portion of the inner container. In embodiments in which the inner container is attached to a rigid backing member is provided with attachment means, for example the backing member may be shaped, for example as a hook to provide the attachment means.

10 The attachment means provides a means to locate the dispenser near to the patient for example by attachment to the bed or cot rail so that the medicament vapour diffuses slowly from the inner container. Thus the medicament vapour can be inhaled by the patient for  
15 example when asleep to provide a long lasting effect.

A further advantage of the pack of the present invention is that the rate of diffusion of the medicament vapour from the pack may be controlled by the nature of the absorbent substrate and permeability of  
20 the inner container.

The dispensers of the present invention may be manufactured by impregnating a solid substrate with the liquid medicament and sealing the impregnated substrate inside the inner container. The impregnated substrate  
25 may be placed between two sheets of a plastics material which is impermeable to the liquid medicament and the sheets sealed around their periphery to enclose the substrate inside the inner container. At least one of the sheets should be permeable to the vapour of the  
30 medicament. Alternatively the substrate may be placed inside a pouch of a vapour-permeable plastics material which is subsequently sealed at its open end to enclose the substrate. The substrate may be impregnated before

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it is placed inside the pouch or after the substrate has been inserted. In an alternative, the liquid medicament may be placed in the pouch prior to the insertion of the substrate. The impregnated substrate inside the inner  
5 container is then placed inside the outer container. The outer container may be formed from two sheets of plastics material which are sealed around their periphery or it may be a pouch sealed on three sides into which the inner container is placed prior to  
10 sealing the outer container.

In embodiments in which the outer container is formed by a film attached to a rigid backing member, the dispenser may be assembled by placing a substrate impregnated with the liquid medicament on the backing  
15 member, placing a film of vapour-permeable material over the substrate and sealing that film to the backing member around its periphery to form an inner container and then placing a film of vapour-impermeable material over the inner container and sealing it around its  
20 periphery to the backing member.

Before use the outer container prevents leakage of either vapour or liquid medicament. In use the outer container is opened, which allows the medicament vapour to diffuse slowly through the inner container, to be  
25 inhaled by the user. The medicament liquid remains within the inner container absorbed onto the substrate.

Specific embodiments of the invention will now be described with reference to the accompanying drawings in which:-

30 Figure 1 is a plan view of a first embodiment of the present invention,

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Figure 2 is a cross-sectional view of a second embodiment of the present invention, and

Figure 3 is a plan view of the second embodiment shown in Figure 2.

5       The dispenser shown in Figure 1 contains a single dose of a Karvol (RTM) liquid decongestant inhalation product. The impregnated substrate is located between two sheets 2,3 of a microperforated plastics material which are sealed together around their periphery, for  
10       example by heat sealing, to form an inner container enclosing the impregnated substrate. The inner container is then placed between two sheets 4,5 of material which are impermeable to the vapour of the medicament and which are sealed around their periphery  
15       to prevent any loss of medicament vapour until the seal is broken by the user. If the outer container is made of a plastics material such as a polyvinylchloride polymer coated on what will be the inner surface of the outer container with a further plastics material such as  
20       a polyvinylidene chloride polymer, the sealing may be performed by heat sealing or radio frequency welding. If the sheets have a coating or film of aluminium then the sealing must be performed by the use of an adhesive. To use the dispenser, the seal of the outer container is  
25       broken and the inner container is removed. This allows the volatile, aromatic Karvol (RTM) vapour to diffuse slowly from the inner container to be inhaled by the user.

30       In the embodiment shown in Figures 2 and 3, a substrate 11 impregnated with a volatile liquid medicament is located on a backing member 10 which is made of a material which is impervious to the liquid medicament and to the vapour of the medicament. Preferably the backing member 10 is made from a rigid

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plastics material. The impregnated substrate 11 is retained in position by a vapour permeable film 12 which is sealed around its periphery to the backing member 10 by a seal 13. A further film 14 of vapour impermeable material is sealed to the backing member 10 by a peripheral seal 15 which is located outside the seal 13. The further film may be provided with areas of weakness (not shown) which allow a central portion of the further film 14 to be removed to allow the medicament vapour to escape. Alternatively the seal 15 may be such that the further film 14 can be removed from the backing member 10. The backing member 10 is shaped in the form of a hook 16 to enable the dispenser to be hung near the patient for example on the rail of a child's cot.

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CLAIMS

1. A dispenser for administering a volatile liquid medicament comprising an inner container adapted to hold the liquid medicament, said inner container being permeable to vapour from the medicament, but substantially impermeable to the liquid medicament, and an outer container within which the first retaining means has been sealed, the outer container being impermeable to the medicament as liquid or vapour.
2. A dispenser as claimed in claim 1 in which an absorbent substrate for the liquid medicament is provided within the inner container.
3. A dispenser according to any preceding claim, in which the absorbent substrate is a fabric, a synthetic or natural sponge, a foamed plastics woven or non-woven material or paper.
4. A dispenser according to claim 3, in which the substrate is tissue paper.
5. A dispenser as claimed in any preceding claim in which the inner container comprises over all or part of its surface a microperforated plastics material.
6. A dispenser as claimed in claims 1 to 5 in which the inner container is formed from two sheets of vapour-permeable but liquid-impermeable material sealed together around their periphery to enclose the liquid medicament and the outer container is formed from two sheets of vapour-impermeable material sealed together around their periphery to enclose the inner container.

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7. A dispenser as claimed in claim 6 in which the inner container is provided with attachment means.

8. A dispenser as claimed in any preceding claim in which the inner container is formed by sealing a film of vapour permeable material around its periphery to a rigid plastics backing member to enclose the liquid medicament and the outer container is formed by sealing a film of vapour impermeable material around its periphery to the backing member to enclose the inner container.

9. A dispenser as claimed in claim 8 in which the backing member is provided with attachment means.

10. A dispenser as claimed in any preceding claim wherein the liquid medicament is a liquid decongestant inhalation product comprising an aromatic mixture of pine oil, cinnamon oil and menthol.

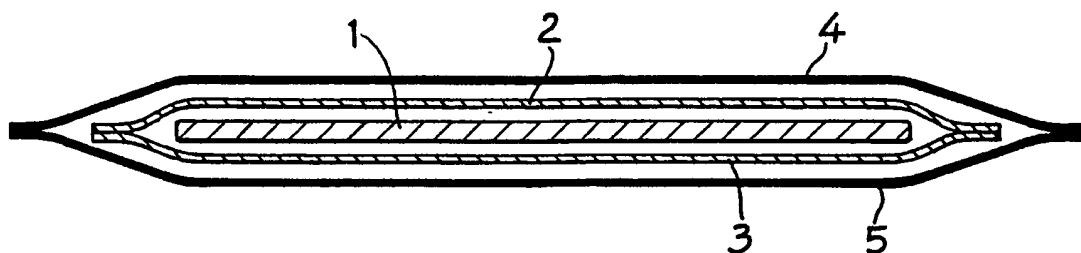


Fig. 1

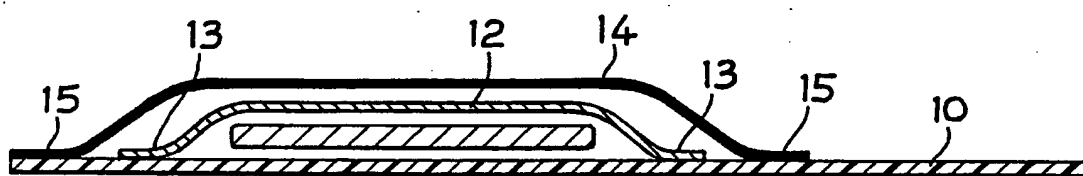


Fig. 2

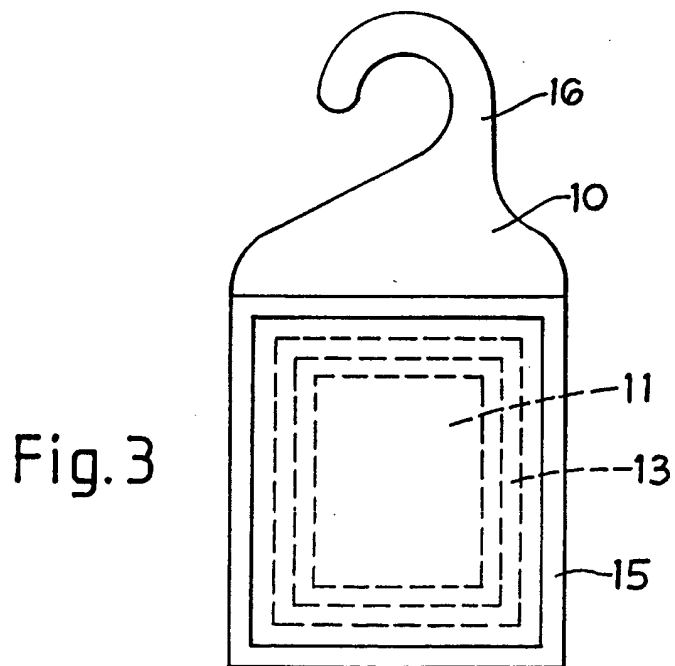


Fig. 3

## INTERNATIONAL SEARCH REPORT

Int. l. Application No

PCT/EP 94/00513

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 5 A61M15/08 B65D75/38 B65D75/30 B65D75/56

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 5 A61M A61J A61B B65D A45D A01M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP,A,0 019 010 (HYMANN) 26 November 1980 see page 7, line 30 - page 8, line 24 see page 9, line 33 - page 10, line 10	1-5, 8, 10
Y	see page 14, line 1 - line 2; figures ---	9
X	EP,A,0 131 759 (DR. WERNER FREYBERG ET AL.) 23 January 1985	1, 5, 6
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A	US,A,2 630 802 (ARPIN) 20 September 1950 see the whole document -----	1

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US-A-2630802		NONE	